UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA

RYAN BERGSTRESSER,	:	**CIVIL ACTION NO. 3:12-1464**
Plaintiff	:	
v.	:	**(JUDGE MANNION)**
BRISTOL-MYERS SQUIBB COMPANY,	:	
Defendant	:	

M E M O R A N D U M

Pending before the court is the defendant's motion to dismiss the plaintiff's first amended complaint. (Doc. No. 19)[1]. Based upon the court's review of the motion and related materials, the defendant's motion to dismiss will be granted as discussed herein.

I. PROCEDURAL HISTORY

By way of relevant background, the plaintiff originally filed the instant action on July 5, 2012, in the Court of Common Pleas of Lackawanna County, in which he alleges that he suffered personal injuries as a result of taking the prescription medication Abilify. The plaintiff set forth claims of negligence, strict liability and breach of implied warranty. (Doc. No. 1, Ex. 1). On July 30,

[1]The motion further requests oral argument. However, the court finds that the briefing filed by the parties is sufficient to decide the motion and that oral argument is therefore unnecessary at this time.

2012, the defendant removed the action to this court based upon diversity jurisdiction. (Doc. No. 1). On the same day, the defendant filed an answer to the plaintiff's complaint. (Doc. No. 3).

On September 7, 2012, the defendant filed a motion for judgment on the pleadings. Upon completion of briefing, by memorandum and order dated April 24, 2013, the court granted in part and denied in part the defendant's motion. See Bergstresser v. Bristol-Myers Squibb Company, 2013 WL 1760525 (M.D.Pa. Apr. 24, 2013). Specifically, the court determined that the only claims raised by the plaintiff which could potentially proceed would be a strict liability claim based upon a manufacturing defect and a negligence claim based upon failure to warn. The court determined, however, that the plaintiff's complaint, as filed, failed to set forth sufficient factual allegations to support those claims. Upon his request, the plaintiff was given an opportunity to cure the deficiencies of his complaint by filing an amended complaint.

On May 16, 2013, the plaintiff filed his amended complaint, which sets forth a sole claim of negligent failure to warn. (Doc. No. 18). On June 3, 2013, the defendant filed the pending motion to dismiss the plaintiff's amended complaint, (Doc. No. 19), along with a brief in support thereof, (Doc. No. 20). The plaintiff filed a brief in opposition to the defendant's motion on July 1, 2013. (Doc. No. 27). On July 11, 2013, the defendant filed a reply brief. (Doc.

No. 30).

II. LEGAL STANDARD

In deciding the defendant's motion, the court must read the complaint in the light most favorable to the plaintiff and all well-pleaded, material allegations in the complaint must be taken as true. Estelle v. Gamble, 429 U.S. 97 (1976). However, the court need not accept inferences drawn by the plaintiff if they are unsupported by the facts as set forth in the complaint. See California Pub. Employee Ret. Sys. v. The Chubb Corp., 394 F.3d 126, 143 (3d Cir. 2004) (citing Morse v. Lower Merion School Dist., 132 F.3d 902, 906 (3d Cir. 1997)). The court also need not accept legal conclusions set forth as factual allegations. Bell Atlantic Corp. v. Twombly, 550 U.S. 554, 555 (2007) (citing Papasan v. Allain, 478 U.S. 265, 286 (1986)).

A viable complaint must include "enough facts to state a claim to relief that is plausible on its face." Twombly, 550 U.S. at 554 (rejecting the traditional 12(b)(6) standard set forth in Conley v. Gibson, 355 U.S. 41, 45-46 (1957)). "Factual allegations must be enough to raise a right to relief above the speculative level." Id. at 555. See also Ashcroft v. Iqbal, 556 U.S. 662 (2009) (holding that, while the complaint need not contain detailed factual allegations, it must contain more than a "formulaic recitation of the elements"

of a claim and must state a claim that is plausible on its face) (quoting Bell Atlantic Corp. v. Twombly, supra, and providing further guidance on the standard set forth therein).

In deciding the defendant's motion, the court should generally consider only the allegations contained in the complaint, the exhibits attached to the complaint, matters of public record, and "undisputably authentic" documents which plaintiff has identified as the basis of his claim. See Pension Benefit Guarantee Corp. v. White Consolidated Industries, Inc., 998 F.2d 1192, 1196 (3d Cir. 1993).

III. DISCUSSION

In his amended complaint, the plaintiff alleges that, at all relevant times, the defendant was engaged in the business of manufacturing, compounding, packaging, labeling and distributing the prescription drug Abilify and promoted Abilify as efficacious and safe for use by consumers, although it knew, or in the exercise of reasonable diligence should have known, that it was not efficacious and safe for all consumers.

In distributing Abilify, the plaintiff alleges that the defendant provides certain warnings and warning labels to the doctors who would prescribe the medication, but nowhere in those warnings does the defendant warn of the

potential to contract the muscular disease of dystonia, which is a prolonged involuntary muscular contraction that may cause twisting of body parts, repetitive movements, and increased muscular tone. Instead, the plaintiff alleges that the defendant warns of a potential risk for tardive dyskinesia[2]. In the event that symptoms of a muscular movement develop, the defendant's warnings indicate that they may be potentially irreversible. However, the plaintiff alleges that the defendant's warnings fail to provide instructions to physicians on how to monitor signs and symptoms of any version of dystonia or tardive dyskinesia so as to prevent contraction of these conditions or their potentially irreversible symptomatology.

The amended complaint further alleges that the defendant failed to provide any directions, education or recommendations as to how the prescribing physician should increase or decrease the strength or dosage of the medication when prescribing it for depression-like symptoms in order to limit or prevent contraction of dystonia or tardive dyskinesia.

The plaintiff was prescribed Abilify by his treating psychiatrist. Initially, the plaintiff was prescribed 10 mg to help counteract his depression.

---

[2]Tardive dyskinesia is a neurological syndrome marked by slow, rhythmical, automatic stereotyped movements, either generalized or in single muscle groups. These occur as an undesired effect of therapy with certain psychotropic drugs, especially the phenothiazines. Taber's Cyclopedic Medical Dictionary at 624 (19th ed. 2001).

According to the plaintiff, his treating physician did not provide any treatment plan or recommendations about what, if any, potential side effects of which he should be aware.

On or about July 30, 2010, the plaintiff's dosage of Abilify was increased from 10 mg to 15 mg. The plaintiff alleges that his treating psychiatrist was provided no warnings and/or treatment protocol by the defendant as to what, if any, monitoring should be performed when increasing a dosage so as to educate his patient. The plaintiff was provided no education as to what, if any, symptoms to lookout for so as to be aware of the potential side effect of dystonia. Within one month of taking the increased dosage of Abilify, the plaintiff began experiencing symptoms of dystonia.

In the beginning of September 2010, the plaintiff alleges that he returned to his physician who discontinued the Abilify. Based on his exposure to the increased dosage of Abilify without the proper warnings and recommendations for observance and treatments of side effects, the plaintiff alleges that he has sustained permanent dystonia.

In his amended complaint, the plaintiff alleges that the defendant had a duty to provide adequate warnings to his treating physician for prescribing Abilify and for appropriate monitoring in increasing the dosage of Abilify, but failed to provide proper instructions for monitoring and observing potential

side effects of Abilify. Had the defendant provided appropriate and sufficient recommended monitoring for the usage of Abilify, the plaintiff alleges that he may not have contracted dystonia. The plaintiff alleges that his contraction of dystonia was a direct and proximate result of the defendant's failures as set forth above.

In its motion to dismiss, the defendant argues that the plaintiff's failure to warn claim is inadequately pled because the plaintiff fails to explain how alternative warnings would have prevented the plaintiff's physician from prescribing Abilify. In addition, the defendant argues that, contrary to the court's prior memorandum and order, the plaintiff ignores the actual warnings on the Abilify label and therefore fails to point to any deficiencies in the labeling or identify the alternative warnings that the defendant should have given.

As the court set forth in its prior memorandum, in order to state a claim for negligent failure to warn under Pennsylvania law, the plaintiff must show: "that the manufacturer owed a duty to the plaintiff; that the manufacturer breached that duty; and such breach was the proximate cause of plaintiff's injuries." Salvio v. Amgen, Inc., 810 F.Supp.2d 745, 752-53 (W.D. Pa. 2011) (citing Parkinson v. Guidant Corp., 315 F.Supp.2d 741, 749 (W.D.Pa. 2004)). See also Dauphin Deposit Bank & Trust v. Toyota, 596 A.2d 845, 849-50

(Pa.Super. 1991)); Oddi v. Ford Motor Co., 234 F.3d 136, 144 (3d Cir. 2000). Further, in a negligence claim based upon failure to warn, the plaintiff must prove that the manufacturer was at fault. Id. (citing Parkinson, 315 F.Supp.2d at 749).

Where a case involves a negligent failure to warn regarding a pharmaceutical drug, the Pennsylvania courts have adopted the "learned intermediary doctrine" stating:

> [T]he manufacturer of a prescription drug known to be dangerous for its intended use, has a duty to exercise reasonable care to inform those for whose use the article was supplied of the facts which make the product likely to be dangerous. However, the warnings which are required to be given by the manufacturer must be directed to the physician, not the patient-consumer. This is so because it is the duty of the prescribing physician to be fully aware of (1) the characteristics of the drug he is prescribing, (2) the amount of the drug which can be safely administered, and (3) the different medications the patient is taking. It is also the duty of the prescribing physician to advise the patient of any dangers or side effects associated with the use of the drug as well as how and when to take the drug. The warnings which must accompany such drugs are directed to the physician rather than to the patient-consumer as it is for the prescribing physician to use his independent medical judgment, taking into account the data supplied to him from the manufacturer, other medical literature, and any other sources available to him, and weighing that knowledge against the personal medical history of his patient, whether to prescribe a given drug. Thus, in an action against a drug manufacturer based upon inadequate warnings, the issue to be determined is whether the warning, if any, that was given to the prescribing physicians was proper and adequate.

Id. (citing Daniel v. Wyeth Pharms., Inc., 15 A.3d 909, 924 (Pa.Super. 2011)

(quoting Taurino v. Ellen, 579 A.2d 925, 927 (Pa.Super. 1990), *appeal denied*, 589 A.2d 693 (Pa. 1991)). Where the manufacturer provides proper warning to a consumer's physician, it will have discharged its duty to the consumer.

In considering the negligent failure to warn claim raised in the plaintiff's original complaint, the court noted that the plaintiff had neither addressed the warnings which were, in fact, provided on the Abilify label, nor did he point to any deficiencies in the labeling. Further, the plaintiff failed to indicate what warning should have been given or that any alternative warning would have prevented his physician from prescribing him Abilify. Bergstresser, 2013 WL 1760525 at *5 (citing Demmler v. SmithKline Beecham Corp., 671 A.2d at 1155; Lineberger v. Wyeth, 2005 WL 1274458, *3 (Pa.Ct.Com.Pl. May 23, 2005). Thus, the court concluded that the allegations of the plaintiff's original complaint were insufficient to state a claim for negligent failure to warn.

In bringing his amended complaint, as argued by the defendant, the plaintiff still fails to address the warnings which are, in fact, provided on the Abilify packaging label. To this extent, he alleges that "nowhere" in the Abilify package insert did the defendant warn of the potential to contract dystonia. Despite this allegation, in the package insert, Section 6, "Adverse Reactions," sub-section 6.2 "Clinical Studies Experience[3]," extrapyramidal[4] symptoms are

[3]According to the relevant Code of Federal Regulations, prescription (continued...)

indicated for patients being treated for, among other things, major depressive disorder[5]. In addition, there is a separate section titled "Dystonia," which indicates:

---

[3](...continued)
drug labeling must include an "Adverse Reactions" section, which must list "the most frequently occurring" adverse reactions. 21 C.F.R. §§201.57(a)(11), (c)(7). An "adverse reaction" is defined as "an undesirable effect, reasonably associated with the use of a drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence." 21 C.F.R. §201.57(c)(7). The "Clinical Trials Experience" is a sub-section to the "Adverse Reactions" section, which must list the adverse reactions in clinical trials that occurred at or above a specified rate appropriate to the safety database. 21 C.F.R. §201.57(c)(7)(ii)(A). This is distinguished from the adverse reactions which must be included under the heading "Warnings and Precautions," which must include only "the most clinically significant" adverse reactions. 21 C.F.R. §§201.57(a)(10), (c)(6). Adverse reactions which are included elsewhere in the labeling, such as under "Warnings and Precautions" or "Contraindications," must not be repeated in the "Adverse Reactions" section. See 21 C.F.R. §201.57.

[4]Extrapyramidal syndrome is any of several degenerative nervous system diseases that involve the extrapyramidal system and the basal ganglion of the brain. The symptoms include tremors, chorea, athetosis, and dystonia. Taber's Cyclopedic Medical Dictionary at 730 (19th ed. 2001) (emphasis added). Extrapyramidal symptoms are listed as an adverse reaction to a majority of the indications for which Abilify is prescribed.

[5]The plaintiff alleges in his amended complaint only that he was prescribed Abilify for depression. Abilify is indicated for adjunctive treatment of major depressive disorder. The plaintiff does not allege in his amended complaint that he was already taking an antidepressant, neither does he allege that Abilify was improperly prescribed by his physician, but only that the medication contained inadequate warnings.

> *Class Effect:* Symptoms of dystonia, prolonged abnormal contractions of muscle groups, may occur in susceptible individuals during the first few days of treatment. Dystonic symptoms include: spasm of the neck muscles, sometimes progressing to tightness of the throat, swallowing difficulty, difficulty breathing, and/or protrusion of the tongue. While these symptoms can occur at low doses, they occur more frequently and with greater severity with high potency and at higher doses of first generation antipsychotic drugs. An elevated risk of acute dystonia is observed in males and younger age groups.

(Doc. No. 18, Ex. A, p. 38).

In his brief opposing the defendant's motion to dismiss, the plaintiff argues that reference to information in the package labeling raises a factual dispute in terms of the adequacy of the warnings and labelings which is inappropriate for consideration on a motion to dismiss. However, under Pennsylvania's learned intermediary doctrine, the determination of whether a warning provided to a prescribing physician is adequate is initially a question of law. See Salvio v. Amgen, Inc., 2012 WL 517446, * 4 (W.D.Pa. Feb. 15, 2012) (citing Mazur v. Merck & Co., Inc., 964 F.2d 1348, 1366 (3d Cir. 1992)). See also Fletcher v. Raymond Corp., 623 A.2d 845, 848 (Pa.Super. 1993); Demmler v. SmithKline Beecham Corp., 671 A.2d 1151, 1154 (Pa.Super. 1996). Thus, the court finds consideration of the labeling

information appropriate in relation to the instant motion to dismiss.

Although the plaintiff fails to address the above labeling language in his amended complaint, in his brief opposing the defendant's motion to dismiss, the plaintiff further argues that ". . . simply because [the defendant] placed the definition of Dystonia within its labeling . . ." was not sufficient to warn of the potential to contract dystonia. However, it is clear from the above language that the Abilify package insert does not simply define dystonia, but identifies the contraction of dystonia as a possible reaction to taking Abilify. Because the plaintiff fails to allege in his amended complaint how this information was inadequate to warn his treating physician about the potential to contract dystonia as a result of taking Abilify, what additional information should have been provided, or how any additional information would have prevented his physician from prescribing Abilify resulting in a prevention of his injury, this basis of his failure to warn claim is insufficient.

Further, the plaintiff alleges in his amended complaint that the defendant failed to provide adequate warning with respect to how the prescribing physician should increase or decrease the strength or dosage of Abilify when prescribing it for symptoms of depression, and failed to provide any direction to prescribing physicians as to how to slowly or incrementally increase dosages to provide treatment for patients suffering with depression

in order to limit or prevent the contraction of dystonia.

As to these allegations, the first page of the package insert, which contains "Highlights of Prescribing Information," includes a section titled "Dosage and Administration." This section breaks down for each of the indications for which Abilify could be prescribed, including as an adjunct to antidepressants for the treatment of major depressive disorder[6], the initial dose, the recommended dose and the maximum dose. Further, within the package insert, at Section 2 titled "Dosage and Administration," additional specific dosing instructions are provided for each of the indications for which Abilify is prescribed. In Section 2.3, "Adjunctive Treatment of Major Depressive Disorder," it is indicated:

> *Adults*
>
> Dose Selection - The recommended starting dose for ABILIFY as adjunctive treatment for patients already taking an antidepressant is 2 mg/day to 5 mg/day. The efficacy of ABILIFY as an adjunctive therapy for major depressive disorder was established with a dose range of 2 mg/day to 15 mg/day. Dose adjustments of up to 5 mg/day should occur gradually, at intervals of no less than 1 week [*see CLINICAL STUDIES (14.3)]*.
>
> Maintenance Treatment - The efficacy of ABILIFY for the adjunctive maintenance treatment of major depressive disorder has not been evaluated. While there is no body of evidence available to answer the

[6] See n.5.

> question of how long the patient treated with ABILIFY should be maintained, patients should be periodically reassessed to determine the continued need for maintenance treatment.

(Doc. No. 18, Ex. A, p. 9).

Thus, the packaging insert does contain dosing information for patients being treated with Abilify for indications of depression. Again, the plaintiff neither addresses this label information in his amended complaint nor does he allege how the information provides inadequate warning to physicians with respect to the dosage and administration of Abilify for patients being treated for symptoms of depression, what additional information should have been provided, or how that information would have prevented his physician from prescribing Abilify resulting in a prevention of his injury. Thus, this basis of the plaintiff's failure to warn claim is insufficient.

Finally, the plaintiff alleges that the package insert does not provide any information with respect to what, if any, monitoring care the prescribing physician should engage in to be prepared for and potentially prevent contraction of dystonia or tardive dyskinesia when taking Abilify.

Despite the plaintiff's allegations, the package insert does contain monitoring information with respect to tardive dyskinesia. In the "Highlights of Prescribing Information," under the "Warnings and Precautions" section, the Abilify package insert indicates, in relevant part, "Tardive Dyskinesia:

Discontinue if clinically appropriate (5.4).” Section 5.4 of the package insert then reads:

> **5.4 Tardive Dyskinesia**
>
> A syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with antipsychotic drugs. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to rely upon prevalence estimates to predict, at the inception of antipsychotic treatment, which patients are likely to develop the syndrome. Whether antipsychotic drug products differ in their potential to cause tardive dyskinesia is unknown.
>
> The risk of developing tardive dyskinesia and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic drugs administered to the patient increase. However, the syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses.
>
> There is no known treatment for established cases of tardive dyskinesia, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn. Antipsychotic treatment, itself, however, may suppress (or partially suppress) the signs and symptoms of the syndrome and, thereby, may possibly mask the underlying process. The effect that symptomatic suppression has upon the long-term course of the syndrome is unknown.
>
> Given these considerations, ABILIFY should be prescribed in a manner that is most likely to minimize the occurrence of tardive dyskinesia. Chronic antipsychotic treatment should generally be reserved for patients who suffer from a chronic illness that (1)

> is known to respond to antipsychotic drugs and (2) for whom alternative, equally effective, but potentially less harmful treatments are not available or appropriate. In patients who do require chronic treatment, the smallest doses and the shortest duration of treatment producing a satisfactory clinical response should be sought. The need for continued treatment should be reassessed periodically.
>
> If signs and symptoms of tardive dyskinesia appear in a patient on ABILIFY, drug discontinuation should be considered. However, some patients may require treatment with ABILIFY despite the presence of the syndrome.

Thus, the package insert does contain monitoring information relevant to tardive dyskinesia and any claim by the plaintiff to the contrary is without merit.

Further, although the package labeling defines dystonia, and advises physicians that the contraction of dystonia is a possible side effect of taking Abilify and when that risk is believed to most likely occur, there are no specific monitoring instructions with respect to dystonia contained in the packaging label. However, based upon the Code of Federal Regulations, such instructions are not required to be contained in the labeling information for those conditions which are listed only as "adverse reactions." Instead, such instructions are only required with respect to "the most clinically significant

information" listed under the "Warnings and Precautions" section[7]. Specifically, the Regulations provide that the "Warnings and Precautions" section must include, among other things, "recommendations for patient monitoring that are critical for safe use of the drug." 21 C.F.R. §201.57(a)(10). No such requirement is provided for those conditions listed under the "Adverse Reactions" section. See 21 C.F.R. §201.57(a)(11).

Aside from the requirements, or lack thereof, of the Code of Federal Regulations to provide monitoring information, to the extent that the plaintiff alleges that the Abilify package labeling does not provide adequate monitoring instructions to physicians regarding the symptoms of dystonia, the plaintiff's allegations overlook the fact that such judgments as to specific monitoring are better left to the physicians' discretion, as opposed to the disassociated drug manufacturer. As outlined above, the law concerning negligent failure to warn is governed by the learned intermediary doctrine which requires that the drug manufacturer provide adequate warnings of the known dangers of a drug to physicians which would permit the physicians to adequately advise their patients of the risks of using the drug. A drug manufacturer has "a duty to exercise reasonable care to inform those for whose use the article [was] supplied of the facts which make [the product] likely to be dangerous." Aaron

[7]The court notes that tardive dyskinesia is listed under the "Warnings and Precautions" section.

v. Wyeth, 2010 WL 653984, *7 (W.D.Pa. Feb. 19, 2010 (citations omitted). Warnings that "advise[] physicians of the specific risks at issue" are adequate as a matter of law. Id. at *10. The law does not require that the drug manufacturer provide such detailed information or instructions so as to remove the medical judgment of the physicians, who are in the best position to monitor and treat their patients and make medical judgments with respect to their care. See e.g., In re Meridia Products Liability Litigation, 328 F.Supp.2d 791, 813-14 (N.D.Ohio 2004).

As a final point on this issue, in dismissing the plaintiff's original negligent failure to warn claim, the court indicated that, in addition to his failure to address the warnings provided in the Abilify package label or any deficiencies in the labeling, the plaintiff failed to indicate what further warning should have been given, or that any alternative warning would have prevented his physician from prescribing Abilify such that his injury would have been avoided. Bergstresser 2013 WL 1760525, at *5 (citing Demmler v. SmithKline Beecham Corp., 671 A.2d 1151, 1155 (Pa.Super. 1996); Lineberger v. Wyeth, 2005 WL 1274458, *3 (Pa.Ct.Com.Pl. May 23, 2005)). The plaintiff has not cured these insufficiencies in his amended complaint as to his monitoring claim. Specifically, although the plaintiff generally alleges that if "Defendant had provided appropriate and sufficient monitoring for the

usage of Abilify, the Plaintiff may not have suffered Dystonia," he still has not alleged factual support for his claim. The plaintiff has not alleged what "appropriate" monitoring information should have been given, or that any such information would have prevented his doctor from prescribing him Abilify and thus prevented his contraction of dystonia, but only that the alleged appropriate information "may" have prevented him from contracting dystonia. In his opposing brief, the plaintiff argues that dismissal along this line essentially rises to the level of requiring proof of proximate cause at the pleadings stage. However, the court is not requiring that the plaintiff provide evidence in support of his factual allegations at this stage of the proceedings, but only that he make the factual allegations which would support the essential elements of his claims as is required under the law. The plaintiff cannot in a conclusory manner simply allege that his injury would not have resulted if his physician was provided with some unspecified information. He must provide sufficient factual allegations as to why the information provided to the intermediary was inadequate, what information should have been provided, and how that information would have caused the intermediary to act differently which would have prevented the plaintiff's injury.

IV. CONCLUSION

On the basis of the foregoing, the defendant's motion to dismiss the plaintiff's amended complaint, (Doc. No. 21), will be granted. An appropriate order shall issue.

s/ *Malachy E. Mannion*
MALACHY E. MANNION
United States District Judge

Date: December 2, 2013

O:\Mannion\shared\MEMORANDA - DJ\2012 MEMORANDA\12-1464-02.wpd